MedWatch Safety Report

3484618-7-00-11

McNeil
Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

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Approved by FDA on 11/15/93

Mfr report #

IND/Dist report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	37 yrs or Date of birth:	( )female (X)male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
(x) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr): 6/1/95

4. Date of this report (mo/day/yr): 03/30/00

5. Describe event or problem

Notification via attorney letter of "Tylenol toxicity". Letter states that in May of 1995, pt was involved in an auto accident. After accident, on 5/12/95, he went on "a binge for 3-4 days" & thereafter took several Extra Strength TYLENOL® acetaminophen Gelcaps for headache relief. Addl info rec'd 11/11/96: Medical records indicate on 6/2/95, pt was hospitalized following 4 days of nausea, vomiting, low grade fever & 2 days of chest pain & SOB. Past hx of APAP use not listed. Tylenol levels reportedly high. D/c'd on 6/6/95; d/c dx=hepatitis B (HEPATITIS) & Tylenol hepatic toxicity (LIVER DAMAGE). On 7/7/95, approx 1 month later, pt was admitted to hospital w/ cc of abdominal pain. Past hx of APAP use not listed. Tx included IV fluids & K flash. On 7/9/95, pt was d/c'd; principal dx=abdominal pain secondary to gastroenteritis & Hep B & C. Addl info rec'd 3/24/00: GI consult of 6/2/95 indicates pt drank 6-12 cans of beer/d. After car injury, pt took PERCOCET®, as well as APAP. He subsequently developed nausea & vomiting & presented with (See Sect C10)

6. Relevant tests/laboratory data, including dates

6/1/96 PT=21, PTT=30, bili=5.4, alk phos=154, ALT=5486, GGT=549; 6/2/96 ECG=nl, high Tylenol level; 7/7/96 bili=2.1, alk phos=121, AST=76, ALT=57, GGT=391; abd US=hepatosplenomegaly fatty infil liver; hepatitis profile=hepatitis B

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

history of smoking 2 packs of cigarettes/day for 20 years; pin in left femur, skin lesions, history of alcohol abuse, history of use of illicit drugs, including IV cocaine as a teenager; allergic to codeine

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL Gelcaps

#2

2. Dose, frequency & route used

#1 unknown dose, po

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 1995; unknown duration

#2

4. Diagnosis for use (indication)

#1 headache relief

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 Unknown

#2

7. Exp. date (if known)

#1 Unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

PERCOCET®, drinks 6-12 cans of beer/day (Sect B5 cont): jaundice. MD's impression=acute hepatocellular injury, w/ intrahepatic cholestasis (CHOLESTATIC JAUNDICE) secondary to acute APAP toxicity, in combination w/ ethanol.

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

APR 04 2000

APR 04 2000 CDR EVALUATION AND RESEARCH

2. Phone number: 215-273-7303

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
(x) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 03/24/00

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
( ) initial (X) follow-up # 2

8. Adverse event term(s)

LIVER DAMAGE HEPATITIS
JAUNDICE CHOLES

9. Mfr. report number

0658549A

E. Initial reporter

1. Name, address & phone #

[redacted]

DSS 941-377-4555

APR 05 2000

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes ( ) No	physician	( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.